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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,731	09/29/2003	Takahiro Imada	K-1970DIV	6740

32628 7590 11/07/2007

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
11/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,731	IMADA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/24/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 8/24/07 is acknowledged. Claims 4-7 are being considered on the merits.

The information disclosure statement filed 8/24/07 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e) and it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for plants of the genera any *Agrostis, Festuca, Poa* or *Lolium* wherein which the artificial and permanent introduction of certain strains of *Neotyphodium* has been effected. There is nothing in the as-filed specification to indicate or suggest a period of time that the infection remains in the plant or that the introduction is, in fact, permanent. In the specification there are no clear results to show that the infection with *Neotyphodium* is carried in the seeds.

Insertion of the limitation "permanently introduced" by artificial introduction of certain strains of *Neotyphodium* does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of plants having the fungus "permanently introduced". The statement in the specification:

"[0046] (4) Tests using a Later Generation
[0047] Seeds in which the endophyte was present were collected and germinated. After the endophyte was confirmed, the tests described above were performed."

This is not sufficient support for the new genus of "grasses having *Neotyphodium* permanently introduced". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "permanently" in this context is considered to be the insertion of new matter for the above reasons.

In addition, no clear basis or support is found in the present specification for plants of the genera *Agrostis, Festuca, Poa* or *Lolium* within which certain strains of *Neotyphodium* produce chanoclavine as the final metabolic product.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-7 are rejected under 35 U.S.C. 101 because the claims read on plants that are found in nature and thus, are unpatentable to applicant.

While claim 4, recites "artificially and permanently introduced" as a product by process limitation, the plant as claimed cannot be readily distinguished from the naturally occurring plant, since the microorganisms were obtained from a grass, into which the fungus was presumably also permanently introduced, in the absence of evidence to the contrary. Thus fungi are naturally found as symbionts on grasses.

That the fungus can be a symbiont of certain grasses and was isolated therefrom does not imply that just by "artificial and permanent introduction" by any means and in any amount the fungal strain will become permanently installed in any *Agrostis, Festuca, Poa* or *Lolium*, such that the grass is in fact permanently altered.

As to claim 5, there is no clear indication that a seed obtained from an adult grass that has been infected does in fact contain the symbiotic fungus

Regarding claims 6-7, there is no assurance that the plant grown from an infected seed, will in fact be infected. But even if it does, the plant cannot be readily distinguished from the naturally occurring plant, as claimed.

There is no claim designated limitation to clearly delineate a change in the grass that would distinguish the plant from a naturally occurring grass. The mode and effect of "artificial introduction and permanent" does not affect the plant *per se*. Moreover, the extent of "permanent introduction" cannot be readily assessed, since this is not a term found or defined in the present written disclosure as-filed.

There is no claim designated limitation to clearly delineate a change in the grass that would distinguish the plant from a naturally occurring grass. The mode and effect of "artificial introduction and permanent introduction" does not affect the properties of the plant *per se,* in the absence of evidence to the contrary.

Consequently, the claims do not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Innoculant Co.., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

Response to Arguments

Applicant's arguments and Imada Declaration have been fully considered but they are not deemed to be persuasive.

The declaration is defective in that there is no identification of the specific plant used or the "filamentous fungus" provided to the plant. Applicant has not provided objective data to substantiate the identity of the material photographed. Moreover, the photographs cannot be interpreted, since they are illegible as scanned in.

In the declaration, it is stated under 4. that seeds germinated from the unidentified grass harbor the "filamentous fungus". However, neither the grass nor the fungus are identified with any specificity.

In addition, applicant has not demonstrated with objective evidence that the naturally occurring plant that harbors the fungus naturally is not permanently infected with the fungus.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is confusing in that the step of "is artificially introduced" does not specify with any particularity the site or mode of "introduction" or the amount to be "introduced" artificially. Similarly the phrase "permanently introduced into said grass" is not particularly defined in the as-filed specification, and it is unclear what it is intended to encompass.

Claim 6 is confusing in the recitation "a grass... wherein said grass comprises an adult grown from...seed...", since it cannot be readily assessed whether the grass as claimed is or is not infected with the symbiotic fungus.

Claim 7 is vague and indefinite in that there is no clear claim limitation as to whether the hybrid grass intended is or is not infected by the symbiotic fungus or to what extent or the identity of the "adult". Clarification as to the nature of "the parent" is requested. Only one parent appears to be indicated for a "hybrid".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter *et al.*

The claims are broadly drawn to any *Agrostis, Festuca, Poa* or *Lolium,* which has been inoculated with certain strains of *Neotyphodium.*

Porter discloses a plant which is infected with an endophyte that produces chanoclavine.

It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 874). It is noted that ryegrass belongs to the genus *Lolium.*

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cagas *et al.*.

The claims are broadly drawn to any *Agrostis, Festuca, Poa* or *Lolium,* which has been inoculated with certain strains of *Neotyphodium.*

Cagas *et al.* discloses a plant which is infected with an endophyte that produces chanoclavine, such as *Neotyphodium*. It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 366). It is noted that plants such as *Lolium* and *Festuca* are infected.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments and Imada Declaration have been fully considered but they are not deemed to be persuasive.

The declaration is defective in that there is no identification of the specific plant used or the "filamentous fungus" provided to the plant. Applicant has not provided objective data to substantiate the identity of the material photographed. Moreover, the photographs cannot be interpreted, since they are illegible as scanned in.

In the declaration, it is stated under 4. that seeds germinated from the unidentified grass harbor the "filamentous fungus". However, neither the grass nor the fungus are identified with any specificity.

In addition, applicant has not demonstrated with objective evidence that the naturally occurring plant that harbors the fungus naturally is not permanently infected with the fungus.

Applicant has not provided evidence to show that within a plant as claimed, one of the recited strains does, in fact product chanoclavine as the final metabolic product within the plant as now claimed.

Applicant persists to argue that the claims are not "product by process". Yet the claim 4 as written is to:

4. (Currently amended) A grass selected from the group consisting of *Agrostis, Festuca, Poa* and *Lolium,* the grass comprising

a symbiotic fungus artificially and permanently introduced into said grass, wherein said symbiotic fungus is a filamentous fungus belonging to the genus *Neotyphodium,* said symbiotic fungus is one selected from the group consisting of FERM BP-08480, FERM BP-08481 and FERM BP-08482, deposited at the Japanese National Institute of Bioscience and Human Technology, and said symbiotic fungus produces chanoclavine as the final metabolic product within said grass.

The claims are directed to any *Agrostis, Festuca, Poa* or *Lolium* plant having certain *Neotyphodium* strains "artificially and permanently introduced". The product by process aspect of the invention is the "introduction" step, as in "artificially and permanently introduced" is a process step. Applicant's arguments directed to vehicles and typewriters "comprising" a certain feature are noted. However, the instant plant does not merely "comprise" a fungus, but is directed specifically to the method or process by which the fungus is delivered to the plant.

In addition, the fungus is recognized in the art to be a symbiont of certain grasses and was isolated therefrom. Thus the grass as claimed cannot be readily distinguished from other grasses of the same species harboring a fungus that produces chanoclavine.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651